

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

PAUL D. GOLDENHEIM,
16 Hillside Avenue,
Cambridge, MA 02140

Plaintiff,

v.

Civil Action No. _____

KATHLEEN SEBELIUS,
in her official capacity as
SECRETARY, DEPARTMENT OF
HEALTH AND HUMAN SERVICES
200 Independence Ave., S.W.
Washington, DC 20201

and

DANIEL R. LEVINSON,
in his official capacity as INSPECTOR
GENERAL, DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
300 Independence Ave., S.W.
Washington, DC 20201

Defendants.

COMPLAINT FOR DECLARATORY, INJUNCTIVE AND OTHER RELIEF

INTRODUCTION

1. Plaintiff Paul D. Goldenheim is a former senior executive at Purdue Pharma L.P. (“Purdue Pharma” or “the Company”). In this action, plaintiff seeks: (i) a declaratory judgment declaring that a final order issued by the Secretary of the Department of Health and Human Services (“Secretary” and “HHS”) summarily

excluding plaintiff from participation in federal health care programs for twelve (12) years is contrary to law, arbitrary and capricious, an abuse of discretion, and not supported by substantial evidence, in violation of the Administrative Procedure Act, 5 U.S.C. § 706 (“APA”); and (ii) an order vacating and enjoining the exclusion or, alternatively, remanding for further administrative review.

2. The Social Security Act sets forth the circumstances in which the Secretary may exclude individuals convicted of crimes from participating in federal health care programs. 42 U.S.C. § 1320a-7. The exclusion at issue here was based solely on plaintiff’s plea to a no-fault, strict liability misdemeanor under the federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 331(a), 333(a)(1). The misdemeanor charge was based on the FDCA’s “responsible corporate officer” doctrine, an anomaly in the criminal law that permitted plaintiff to be charged and convicted solely because of his status as a senior executive of The Purdue Frederick Company, Inc. (“Purdue Frederick” or “Purdue”) at a time when some Purdue sales personnel made certain misstatements about OxyContin® Tablets, an opioid analgesic. As acknowledged by the prosecutors who brought those charges – and by the court that accepted his plea – the record of conviction contains no accusation and no evidence that Dr. Goldenheim himself committed any unlawful act or that he was aware of any unlawful act committed by other Purdue employees. This is the first time exclusion has ever been imposed based on the “responsible corporate officer” misdemeanor.

3. The grounds for granting the relief sought in this complaint can be summarized as follows:

A. The plaintiff's strict liability misdemeanor plea is not an excludable offense under either of the statutory provisions on which the Secretary has relied, 42 U.S.C. § 1320a-7(b)(1) and (b)(3). Section (b)(1) permits the Secretary to exclude individuals convicted of a misdemeanor "relating to fraud . . . or other financial misconduct," and Section 1128(b)(3) permits exclusion when a person has committed a misdemeanor "relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance." 42 U.S.C. §§ 1320a-7(b)(1), (b)(3). Neither subsection applies here because the plaintiff's responsible corporate officer plea related to plaintiff's status at Purdue, not to his commission of the fraud or controlled substances violations to which the statute refers.

B. The defendants' decision to impose this non-mandatory exclusion was arbitrary and capricious and an abuse of discretion because it does not serve the remedial purposes of the exclusion statute, i.e., barring untrustworthy individuals from participating in federal health care programs and deterring wrongful conduct. Plaintiff has engaged in no misconduct demonstrating untrustworthiness; to the contrary, his plea was not based on any misconduct by him at all but rather on the illegal acts of others. The record shows that throughout his career, plaintiff has demonstrated an unwavering commitment to combating abuse and diversion of prescription drugs.

C. The twelve-year period of this exclusion was an abuse of discretion and not supported by substantial evidence for several reasons. First, it was based on two aggravating circumstances that are not supported by substantial evidence. Since plaintiff was charged based on no misconduct at all, his plea cannot have involved misconduct causing harm to federal health care programs or lasting more than one year. Second, in

reliance on a regulation purporting to limit the mitigating factors that can be considered, the Secretary failed to consider a wealth of mitigating circumstances – including that plaintiff’s plea was based on no misconduct by him nor even knowledge of misconduct, and that he had spent his career fighting abuse of prescription medicines including pain relievers like Purdue’s OxyContin.

PARTIES

4. Plaintiff Dr. Paul Goldenheim is the former Executive Vice President of Medical and Scientific Affairs and Executive Vice President for Worldwide Research and Development of Purdue Pharma and Purdue Frederick. During his employ at Purdue, Dr. Goldenheim resided in Connecticut; he now resides in Massachusetts. On the date of this complaint, Dr. Goldenheim is 59 years old.

5. Defendant Kathleen Sebelius is the Secretary of HHS, a federal department headquartered in Washington, D.C., and is sued in her official capacity only.

6. Daniel R. Levinson is the Inspector General of HHS, with an office located in Washington, D.C., and is sued in his official capacity only.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 702 and 28 U.S.C. § 1331. The Court has authority to issue declaratory and other relief in accordance with 28 U.S.C. §§ 2201(a) and 2202.

8. Venue is proper in this Court under 42 U.S.C. § 405(g), because plaintiff resides within this judicial district.

STATEMENT OF FACTS

A. THE RECORD CONCERNING PLAINTIFF’S MISDEMEANOR PLEA

Purdue Frederick’s Plea

9. Purdue Frederick, an independent, associated entity of Purdue Pharma, developed and originally marketed OxyContin, an opioid analgesic approved by the Food and Drug Administration (“FDA”) in 1995 to treat moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

10. In or about 2002, the United States Attorney’s Office for the Western District of Virginia commenced an investigation into the promotion and sale of OxyContin. On May 10, 2007, Purdue Frederick pleaded guilty to a single felony count of misbranding with intent to defraud in violation of the FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2).

11. The sole factual basis for Purdue Frederick’s felony plea was set forth in an Agreed Statement of Facts. That Agreed Statement of Facts stated, in substance, that prior to July 2001, certain Purdue sales employees deviated from the FDA-approved label by describing OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause withdrawal and tolerance than other immediate-release opioid medications.

12. The government stated that it could not establish that the misbranding caused any harm to federal health care programs or their beneficiaries.

13. The government stated that it could not establish a causal connection between the misbranding statements and abuse and diversion of OxyContin. The sentencing Judge stated that courts consistently have found that despite extensive

discovery, civil plaintiffs have as a matter of law been unable to show that Purdue's actions caused their injuries.

14. The amount of the payments made by Purdue or Purdue Pharma were not calculated or determined based on any evidence of harm or financial loss to federal health care programs or program beneficiaries resulting from the misbranding. There was no such evidence, and the sentencing Judge declined to make any finding that the misbranding caused any financial harm, and also declined to find that any health care program, or any entity, or person was a victim of the misbranding.

Plaintiff's Plea

15. During the relevant period referred to in the Agreed Statement of Facts, plaintiff was the Executive Vice President of Medical and Scientific Affairs and Executive Vice President for Worldwide Research and Development for Purdue.

16. As part of a global resolution of the investigation, plaintiff, together with Michael Friedman, Purdue's President and Chief Executive Officer, and Howard Udell, Purdue's Executive Vice President and Chief Legal Officer, agreed to enter pleas to no-fault strict liability misdemeanor charges of misbranding based on the Agreed Statement of Facts. Under the law stated in *United States v. Park*, 421 U.S. 658 (1975), lack of participation in the wrongdoing was no defense, nor was lack of knowledge or reason to know. The only defense to the "responsible corporate officer" misdemeanor charge was that plaintiff was powerless to prevent the misconduct of others in the first instance or to promptly correct it once discovered, and that defense is unavailable to a senior executive like plaintiff.

17. It is undisputed that the FDCA misdemeanor provision does not require proof of any intent, including fraudulent intent or intent to mislead. The prosecutors stated to the District Court that the plaintiff's misdemeanor offense "requires no proof of intent or actual knowledge of the violations by the Corporate Officials to establish [his] guilt for the misdemeanor offense."

18. There is no evidence in the record that the plaintiff acted with criminal intent, including fraudulent intent or intent to mislead.

19. The government did not allege in the Agreed Statement of Facts or otherwise state to the District Court that the plaintiff acted intentionally or with fraudulent intent or intent to mislead.

20. There is no evidence in the record that plaintiff was made aware of misconduct of other corporate employees and failed to correct or rectify that misconduct.

21. The government did not state to the District Court that the plaintiff was made aware of the misbranding by any person or means and failed to correct or rectify that misbranding.

22. There is no evidence in the record that the circumstances of the misbranding by other corporate employees were such that the plaintiff should have known of that misbranding.

23. The government did not state to the District Court that the circumstances of the misbranding by other corporate employees were such that the plaintiff should have known of that misbranding.

The Exclusion

24. On November 15, 2007, the Office of Inspector General of HHS (the “IG”) sent plaintiff a Notice of Intent to Exclude. In response, plaintiff presented a written submission to the IG detailing reasons that exclusion should not be imposed including, but not limited to, contentions that his misdemeanor plea was not an excludable offense, and that his exclusion would constitute an abuse of agency discretion.

25. By notice dated March 31, 2008, the IG informed plaintiff that he “[is] being excluded from participation in any capacity in Medicare, Medicaid, and all Federal health care programs, as defined in section 1128B(f) of the Social Security Act (Act), for a minimum period of 20 years.” (emphasis in original). The notice also stated that the “action is being taken under sections 1128(b)(3) and 1128(b)(1) of the Act and is effective 20 days from the date of this letter.” The notice relied on plaintiff’s misdemeanor conviction as the basis for exclusion, claiming that “[y]our conviction related to the introduction into interstate commerce by the Purdue Frederick Company, Inc. (Purdue) of OxyContin, a Schedule II controlled substance, that was misbranded in violation of the Food, Drug, and Cosmetic Act.” By similar notices, the IG also informed Michael Friedman and Howard Udell that they were being excluded from participation in all federal health care programs.

26. Section (b)(1), 42 U.S.C. § 1320a-7(b)(1), permits (but does not mandate) exclusion of a person who has been convicted of a misdemeanor “relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.” Section (b)(3), 42 U.S.C. § 1320a-7(b)(3), permits (but does not mandate) exclusion of a person who has been convicted of a misdemeanor “relating to the unlawful manufacture,

distribution, prescription or dispensing of a controlled substance.” These two provisions – Section (b)(1) and Section (b)(3) – are the only statutory authority on which the IG relies to exclude the plaintiff.

27. Under 42 U.S.C. § 1320a-7a(a)(6), an organization that furnishes items or services to federal health care program beneficiaries may be liable for civil monetary penalties and permissive exclusion if it were to place (or keep) an excluded individual within the organization and, under 42 U.S.C. § 1320a-7a(a)(8), would also be subject to permissive exclusion if it were to place (or keep) an excluded individual as an officer, director, agent, or managing employee of the organization. As enforced by the IG, the prohibitions that accompany exclusion virtually preclude plaintiff from gainful employment in a pharmaceutical or health care company that markets products in the United States so long as his exclusion remains in place.

28. The record establishes that Dr. Goldenheim is a career pharmaceutical company executive. He is a physician who has spent nearly his entire working life in pharmaceutical research and development rather than practicing clinical medicine.

Review of the Exclusion

29. Immediately after receiving Notices of their exclusion, plaintiff, together with Messrs. Friedman and Udell, filed a complaint and motion for injunctive relief in District Court, seeking to enjoin their exclusions by the IG pending the outcome of administrative review within HHS and judicial review. *Friedman et al v. Leavitt*, 1:08-cv-00586 (D.D.C. 2008). The Court granted preliminary injunctive relief against enforcement or publication of the exclusions, but on December 5, 2008, the Court ruled

that it lacked subject matter jurisdiction to provide any remedy until plaintiff exhausted his administrative appeal within HHS.

30. Plaintiff pursued his administrative appeals through proceedings before an Administrative Law Judge and ultimately to the Departmental Appeals Board (“DAB”). In the course of pursuing his administrative appeal, plaintiff contested the fact and length of his exclusion on the grounds summarized herein. On August 31, 2009, the DAB issued its decision upholding the plaintiff’s exclusion and imposing a twelve-year exclusion period. The DAB decision is HHS’s final order in the matter. No further administrative review is available.

COUNT I (Against Both Defendants)
Summary Exclusion was Not Authorized by Statute

Paragraphs 1-30 are incorporated by reference herein.

31. The APA prohibits defendants from enforcing the Social Security Act in a manner that is contrary to law or arbitrary and capricious. 5 U.S.C. § 706. The Social Security Act specifies certain limited circumstances in which the Secretary may exclude individuals from participation in federal health care programs.

32. Defendants have excluded plaintiff from federal health care programs under Sections 1128(b)(1) and 1128(b)(3) of the Social Security Act, codified as 42 U.S.C. § 1320a-7(b)(1) and 42 U.S.C. § 1320a-7(b)(3), respectively, based on the record of plaintiff’s plea to the strict liability misdemeanor offense under Sections 331(a) and 333(a)(1) of the FDCA.

33. Based on the record in this case, plaintiff’s strict liability misdemeanor conviction is not an excludable offense as described in Section (b)(1)’s authority to

exclude persons whose convictions “relat[e] to fraud, theft, embezzlement, breach of fiduciary responsibility, or financial misconduct,” nor is it excludable based on Section (b)(3)’s authority to exclude persons whose convictions “relat[e] to the unlawful manufacture, distribution, dispensing or prescription of a controlled substance.”

34. Defendants have exceeded their statutory authority, in violation of the APA and the Social Security Act, by excluding plaintiff without statutory authority to do so.

35. Plaintiff has no adequate remedy at law.

36. Defendants’ exclusion of plaintiff from federal health care programs is causing and will continue to cause substantial, imminent, and irreparable injury to plaintiff.

COUNT II (Against Both Defendants)
Exclusion Was An Abuse of Discretion and Arbitrary and Capricious

Paragraphs 1-36 are incorporated by reference herein.

37. The APA prohibits defendants from enforcing the Social Security Act in a manner that is contrary to law or arbitrary and capricious or an abuse of discretion or unsupported by substantial evidence. 5 U.S.C. § 706.

38. The remedial purposes of the exclusion statute are to protect federal funds and program beneficiaries from untrustworthy individuals and to deter health care fraud.

39. Plaintiff’s strict liability FDCA misdemeanor conviction was based solely on the fact that he was a “responsible corporate officer” at the time other Purdue personnel engaged in misbranding. The plaintiff’s misdemeanor conviction is not based on evidence of his intent, his personal wrongdoing, his knowledge of wrongdoing by others, or circumstances that should have made him aware of the misconduct of others.

40. The remedial purpose of the exclusion statute to protect federal funds and program beneficiaries from untrustworthy individuals is not furthered by exclusion of plaintiff.

41. Nothing in the record of plaintiff's conviction establishes that he was an untrustworthy individual, that his participation would endanger the integrity of federally-funded health care programs, or that he could not be entrusted with well-being and safety of beneficiaries.

42. The remedial purpose of the exclusion statute to deter health care fraud is not furthered by exclusion of plaintiff.

43. Because neither of the statutory purposes would be served through permissive exclusion of the plaintiff, exclusion of him violates the APA in the ways and for the reasons described above.

44. Plaintiff has no adequate remedy at law.

45. Defendants' implementation of its decision to exclude plaintiff from federal health care programs is causing and will continue to cause substantial, imminent, and irreparable injury to plaintiff.

COUNT III (Against Both Defendants)
Exclusion for Twelve-Year Period Violates APA

Paragraphs 1-45 are incorporated by reference herein.

46. The APA prohibits defendants from implementing the Social Security Act in a manner that is contrary to law or arbitrary and capricious or an abuse of discretion or unsupported by substantial evidence. 5 U.S.C. § 706.

47. The Secretary has acknowledged that the lawful period of exclusion is that which will promote the two remedial purposes of the exclusion statute.

48. The remedial purposes of the exclusion statute are to protect federal funds and program beneficiaries from untrustworthy individuals and to deter health care fraud.

49. Plaintiff's strict liability FDCA misdemeanor conviction was based solely on the fact that he was a "responsible corporate officer" at the time other Purdue personnel engaged in misbranding. The misdemeanor offense to which plaintiff pled does not require proof of intent, personal wrongdoing, or even knowledge of wrongdoing by others.

50. The remedial purpose of the exclusion statute to protect federal funds and program beneficiaries from untrustworthy individuals is not furthered by exclusion of the plaintiff for twelve years.

51. Nothing in the record of plaintiff's strict liability, no-intent misdemeanor conviction establishes that the plaintiff was an untrustworthy individual, that he threatened the integrity of federally-funded health care programs, or that he could not be entrusted with well-being and safety of beneficiaries.

52. The remedial purpose of the exclusion statute to deter health care fraud is not furthered by exclusion of the plaintiff for twelve years.

53. Because neither of the statutory purposes would be accomplished through permissive exclusion of the plaintiff, exclusion of him for twelve years violates the APA in the ways and for the reasons described above.

54. The twelve-year period of exclusion also violates the APA because it is not supported by substantial evidence and because it resulted from the Secretary's

impermissible failure to consider significant mitigating circumstances. With respect to the length of exclusion based on a misdemeanor conviction, the Act provides that “the period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances.” 42 U.S.C. § 1320a-7(c)(3)(D).

55. By regulation, HHS has identified the circumstances that qualify under subsection (c)(3)(D) as aggravating.

56. Here, the aggravating circumstances relied upon as the basis for the twelve year exclusion are: that the “acts resulting in the conviction, or similar acts . . . caused, or reasonably could have been expected to cause, a financial loss of \$5,000 or more to a Government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals,” and “the acts that resulted in the conviction, or similar acts, were committed over a period of one year or more.” 42 C.F.R. §§ 1001.201(b)(2)(i),(ii); *see also* 42 C.F.R. § 1001.401(c)(2)(i),(ii).

57. The “acts” at issue cannot be said to have lasted more than one year. The plaintiff’s plea was based on no wrongful act on his part that can be measured against the one-year timeframe. Instead, the plaintiff’s plea was based on his senior position at Purdue. Although the plaintiff held his senior position at Purdue for longer than one year, that does not constitute an aggravating circumstance. Since Dr. Goldenheim committed no wrongful act, the “acts” that resulted in his conviction were not “committed” over a period of one year or longer. Thus, on this record, the defendants’ reliance on “wrongful conduct lasting more than one year” as an aggravating

circumstance was contrary to law, arbitrary, capricious, an abuse of discretion, and not supported by substantial evidence.

58. The record of plaintiff's conviction also contains no substantial basis or evidence to support the second aggravating circumstance on which defendants relied – harm to federal health care programs.

59. The prosecutor stated on the record prior to sentencing that the government lacked any evidence that would enable the court “to identify or quantify the impact [of the misbranding] on prescribing health care providers[.]”

60. Purdue Frederick's counsel and the prosecutors told the District Court that there was no evidence that the government reimbursed for any inappropriate OxyContin prescription that was influenced by, or resulted from, the misbranding at issue.

61. The government stated that it could not establish a causal connection between the misbranding statements and OxyContin abuse and diversion. The sentencing Judge stated that courts consistently had found that despite extensive discovery, civil plaintiffs have as a matter of law been unable to show that Purdue's actions caused their injuries.

62. The amount of the payments made by Purdue Frederick or by Purdue Pharma were not calculated or determined based on any evidence of harm or financial loss to federal health care programs or program beneficiaries resulting from the misbranding. There was no such evidence, and the sentencing Judge declined to make any finding that the misbranding caused any financial harm, and also declined to find that any health care program, or any entity, or person was a victim of the misbranding.

63. On this record, the payment made by Purdue Pharma as “restitution” to federal health care programs does not constitute substantial evidence that the plaintiff’s offense caused or resulted in financial harm to federal health care programs or beneficiaries.

64. The “restitution” payment made by Purdue and Purdue Pharma was part of the global settlement of the investigation. That settlement did not involve exclusion of Purdue Pharma. At all times material to this complaint up to and including the present, Purdue Pharma has marketed OxyContin.

65. On this record, the defendants’ reliance on financial harm to federal health care programs as an aggravating circumstance was contrary to law, arbitrary, capricious, an abuse of discretion, and not supported by substantial evidence.

66. Defendants did not weigh very significant mitigating circumstances, including the undisputed fact that the plaintiff engaged in none of the acts that formed the basis for Purdue Frederick’s plea and was not even aware of them, and the undisputed fact that the plaintiff has spent much of his career at Purdue fighting abuse and diversion of pain relievers like OxyContin.

67. In ignoring these undisputed facts, defendants applied an unduly and impermissibly restrictive regulation purporting to limit the circumstances that qualify under 42 U.S.C. § 1320a-7(c)(3)(D) as mitigating for purposes of determining the length of exclusion. 21 C.F.R. §§ 1001.201 and 1001.401.

68. In determining the twelve-year period of exclusion imposed on the plaintiff, the defendants unduly and impermissibly disregarded and failed to properly weigh as mitigating circumstances certain relevant facts including:

A. That there is no evidence that the misconduct underlying Purdue Frederick's misbranding plea caused financial harm to federal health care programs or beneficiaries.

B. That there is no evidence in the record that plaintiff committed any wrongful act himself, no evidence that he was made aware of misconduct by others, and no evidence that the circumstances of the misbranding by other employees were such that the plaintiff should have known of that misbranding. The sole factual basis for Dr. Goldenheim's misdemeanor plea was his senior executive position at Purdue.

C. That plaintiff, together with Messrs. Friedman and Udell, initiated and implemented substantial and meaningful programs to encourage appropriate prescribing of OxyContin and other pharmaceuticals that are controlled substances, and initiated and implemented valuable programs designed to detect and minimize the abuse and diversion of such pharmaceuticals. They also initiated and implemented programs that were designed to educate and increase awareness of the risks of diversion and abuse of these pharmaceuticals. For example, they cooperated with law enforcement in a myriad of programs that sought to identify those who would divert OxyContin and other pain relievers into channels that lead to abuse. They were the first pharmaceutical company to advocate for Prescription Monitoring Programs aimed at assisting healthcare professionals, regulators, and law enforcement to monitor prescription patterns and detect illegal prescriptions and "doctor shopping." They developed Purdue's Abuse and Diversion Detection Program, under which Purdue's field-based employees notify the Company's Office of General Counsel when they encounter certain indicators of potential abuse or diversion of OxyContin or other controlled substances. They led the

creation of a program to train law enforcement officials in the detection of abuse and diversion; thousands have attended these programs since their inception. They created a system for collecting and using epidemiological data to track abuse and diversion to enable law enforcement and public health to target their resources and effort where they are most needed. They altered the marketing of OxyContin in various ways to combat its diversion, including discontinuing a particular dose that was a focus of abuse. They initiated a program known as RxPATROL, an online pharmacy robber data clearinghouse and partnered with Crime Stoppers by funding rewards for information leading to the apprehension of perpetrators of pharmacy crime, which has contributed to countless investigations and to date nearly 100 reported arrests.

69. Plaintiff has no adequate remedy at law.

70. Defendants' implementation of its decision to exclude plaintiff from federal health care programs for twelve years is causing and will continue to cause substantial, imminent, and irreparable injury to plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for the following relief:

- A. A declaratory judgment
- that plaintiff's exclusion was contrary to law, arbitrary and capricious, an abuse of discretion, and unsupported by substantial evidence, or in the alternative,
 - that plaintiff's exclusion for 12 years was contrary to law, arbitrary and capricious, an abuse of discretion, and unsupported by substantial evidence;

B. Permanent injunctive relief enjoining defendants from further implementing their exclusion of the plaintiff from federal health care programs and from further publicizing that decision on the IG's website or otherwise;

C. An order awarding plaintiff's costs and attorneys fees pursuant to 28 U.S.C. § 2412; and

D. Such other and further relief as the Court deems just and proper.

Dated: October 28, 2009.

Respectfully submitted,

/ S / Peter B. Krupp

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